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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,010	12/30/2003	Randolph J. Noelle	58281US004	7654

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EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,010	NOELLE ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 49-57, drawn to an immunostimulatory composition or vaccine comprising a TLR agonist and the TNF/R agonist, classified in class 424, subclass 184.1, or other class/subclass depending on structure of agonists.

II. Claims 11-48, drawn to a method of inducing T_H1 immune response or activating antigen-specific $CD8^+$ T cells in a subject or treating a condition in a subject comprising administering a TLR agonist and a TNF/R agonist, classified in class 514, subclass 2, or other class/subclass depending on structure of agonists.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to Invention II as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product. For example, T-cells can be stimulated with thalidomide, antibody production can be stimulated by glucocodicosteroids, and immunogenic combinations can be identified with known techniques such as ELISA.

Election of Group I or II further necessitates restriction of invention to one of the following as required under 35 USC 121. Therefore, election is required for **Group I** to one of inventions A-O **and** one of inventions a-x **and** one of inventions i-iv. Election is required for **Group II** to one of inventions B, G, H or I, **and** one of inventions a-x.

TLR agonist:

A. agonist of TLR1

B. agonist of TLR2

C. agonist of TLR3

D. agonist of TLR4

E. agonist of TLR5

F. agonist of TLR6

G. agonist of TLR7

H. agonist of LTR8

I. agonist of TLR9

J. agonist of TLR10

K. an amine compound (*e.g.*, claim 5)

L. MALP-2

M. LPS

N. polyIC

O. CpG

TNF/R agonist:

a. agonist of CD40 ligand

b. agonist of OX40 ligand

c. agonist of4-1BB ligand

d. agonist of CD27

e. agonist of CD30 ligand (CD153)

f. agonist of TNF-α

g. agonist of TNF-β

h. agonist of RANK ligand

i. agonist of LT-α

j. agonist of LT-β

k. agonist of GITR ligand

l. agonist of LIGHT

m. agonist of CD40

n. agonist of OX40

o. agonist of CD70 (CD27 ligand)

p. agonist of CD30

q. agonist of 4-1BB

r. agonist of TNFR2
s. agonist of RANK
t. agonist of LT-βR
u. agonist of HVEM
v. agonist of GITR
w. agonist of TROY
x. agonist of RELT

vaccine antigen:
i. tumor antigen,
ii. viral antigen
iii. bacterial antigen
iv. parasitic antigen

Inventions of A-O, a-x and i-iv are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are functionally and structurally different, thereby exhibiting a different mode of action, and forming a distinct immunostimulatory composition or vaccine. Each compound requires distinct, separate search. Inventions containing A-O are independent or distinct because LPS is a lipopolysaccharide., CpG is an oligonucleotide, polyIC is polyinosinic-polycytidilic acid, MALP-2 is macrophage-activating lipopeptide-2, and each Toll-like Receptor (TLR) has a distinct function and binding characteristic (see, for example, Table 1 and Fig.6 of Beutler et al., Ann Rev. Immunol. 24:353-389, 2006).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873.

Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
May 26, 2006